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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,225	05/04/2001	Kenichiro Shiroyama	Q64175	6389

7590 01/13/2006

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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 01/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/848,225	Applicant(s) SHIROYAMA ET AL.	
	Examiner Lakshmi S. Channavajjala	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7 and 12-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7 and 12-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10-24-05 has been entered.

Claims 7 and 12-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Instant claim 7 recites the limitation wherein the adding of water to the lipid ~~composition is while uniformly mixing the water and the lipid composition while heating~~ at 80 to 120 degrees C, which is not supported by the instant specification. In the Remarks section, applicants point to specification pages 21, 22 and examples 1-5 for the new limitation. However, the paragraph bridging pages 21 and 22 of the specification does not state the claimed temperature. In examples 1-5, it stated that components 1 to 6 in Table 1 were uniformly mixed while heating at 80 to 120 degrees C. However, a careful review of Table 1 does not reveal water in components 1-6. Further, the example describes separate heating of each of the components 7-8, component 9 (water) and components 1-6, which is not the same as "mixing of lipid and

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water while uniformly mixing and the lipid composition while heating at 80-120 C" as claimed. Furthermore, the paragraph describing examples 1 to 5 states that the water containing component was heated to 80-100 degrees C, which is not the same as the new limitation 80-120 degrees C. According to the description from the specification, it is understood that the lipid components are pre-heated to 80 to 120 degrees C, water component is pre-heated to 80-100 degrees C and the two components are mixed while uniformly mixing, which process is different from what has been described because the heating does not occur during mixing. Accordingly, the instant specification fails to provide support for the newly added limitation.

Claims 7 and 12-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Instant claim 7 recites, "while uniformly mixing the water and the lipid composition while heating at 80-120 degrees C", which is vague and indefinite because it is unclear from the expression "while ..mixing...while heating..", as to what is being heated, both lipid and water components separately or one of them or the mixture.

Claim Rejections - 35 USC § 103

Claims 7 and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,221,389 to Cannell et al (Cannell) or Cannell in view of US 5,661,118 to Cauwet or Cauwet in view of Cannell.

Cannell teaches a composition for keratinous tissues comprising a phospholipid that forms bi-layers in aqueous solution, an amphoteric surfactant and a non-ionic surfactant. The delivery system of Cannell overcomes the difficulties of solubilizing lipophilic ingredients such as ceramides (including the 2-oleamido-1,3-octadecanediol), for improving their affinity to skin and hair (col. 2, col. 7, lines 18-20). Cannell teaches that the combination of a phospholipid, nonionic surfactant and amphoteric surfactant in specific percentages (col. 5), for obtaining a clear solution that is suitable for carrying lipophilic ingredients (col. 5; col. 8, lines 58-col. 9, line 9). Among non-ionic surfactants, Cannell teaches compounds such as fatty alcohols, fatty acids or derivatives such as polyoxyethylene derivatives of the same (col. 5, lines 36-55). Cannell also teaches preparing the composition by mixing and heating the carrier components between 65 to 85 degrees C, depending on the melting points of the solid surfactants, and if desired including lipophilic active in the carrier components (col. 9, lines 10-45). Cannell further teaches example 2, which describes the solubility of a ceramide, 2-oleamido-1, and 3-octadecanediol. While Cannell fails to specifically teach a fatty acid component, as claimed, the nonionic surfatcants or the amphoteric surfactants described by Cannell include fatty acids. Further, the Cannell does not teach the same heating temperature, as claimed. However, Cannell suggests heating the components depending on the melting points of the nonionic surfactants and other components of the carrier system. Accordingly, absent evidence to the criticality of choosing the appropriate temperature for heating the carrier components i.e., nonionic surfactants, amphoteric surfactants etc., of Cannell, for providing an efficient carrier for lipophilic components such as

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ceramides would have been obvious for one of an ordinary skill in the art because Cannell teaches preparing a clear solution such as shampoos containing water, for delivering lipophilic components such as ceramides to skin and keratinous tissues.

Cauwet teaches hair and/or skin composition-comprising ceramides, in combination with anionic, amphoteric and other polymers. Cauwet teaches anionic surfactants including fatty acids such as the claimed oleic acid, stearic acid (col. 2, lines 35-39), non-ionic surfactants such polyethoxylated derivatives (col. 13, lines 14-36) and ceramides such as those claimed in the instant invention (col. 11), for improved deposition of ceramides. Cauwet also discuss the combination of cholesterol with ceramide in skin treating compositions. Both Cauwet and Cannell teaches ceramide containing compositions for providing improved skin or hair treatment and both suggests the role of surfactants in improving the delivery of ceramides to the skin and hair.

~~Accordingly, it would have been obvious for one of an ordinary skill in the art at the time~~
of the instant invention to incorporate the specific ceramides, fatty acids and cholesterol of Cauwet in the composition of Cannell or use the carrier system of Cannell in the composition of Cauwet for delivering ceramides of Cauwet because both the references suggest the advantages of ceramide containing composition for skin and hair treatment and Cannell suggests preparing a clear solution that effectively solubilize lipophilic skin or hair care components such as ceramides and their effective delivery to the skin or hair and Cauwet suggests improved deposition of ceramides on the skin and hair.

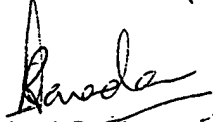
Response to Arguments

Applicant's arguments with respect to claims 7 and 12-14 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Lakshmi S Channavajjala
Examiner
Art Unit 1615

January 4, 2006